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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,540	01/16/2002	Gavriel J. Iddan	P-2752-US	1800
27130	7590	09/22/2004	EXAMINER	
EITAN, PEARL, LATZER & COHEN ZEDEK LLP 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/046,540

Applicant(s)

IDDAN, GAVRIEL J.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 6, 15, 22, 27, 28 and 43 – 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,330,464 to Colvin, Jr. et al. in view of U.S. Patent No. 5,993,378 to Lemelson.

In reference to claims 1 – 6, 15, 22, 27, 28 and 43 – 47, Colvin, Jr. et al. discloses an autonomous device configured for being capable of passing through a body lumen having at least one interaction chamber (14', 14'') for containing a sample while in vivo (Col. 25, lines 51 – 61), the chamber having at least one indicator therein for reacting with the sample for generating optical changes in the chamber; at least one illumination source (18) for illuminating the chamber; and at least one optical detector (20-1, 20-2) for detecting optical changes occurring in the chamber (Col. 6, lines 26 – 56). The chamber is transparent in the wavelength of illumination. Colvin, Jr. et al. discloses a plurality of chambers each having a indicator separate from one another (Col. 12, line 65 – Col. 13, line 2). Each chamber is sealed by a membrane which selectively enables passage of a sample but not of the indicator (Col. 6, lines 51 – 56). Colvin, Jr. et al. discloses receiving an endo-luminal sample in an interaction chamber, the chamber having at least one indicator therein for reacting with the endo-luminal sample for generating optical changes in the chamber; illuminating the chamber; and detecting the optical changes occurring in the chamber (Col. 6, lines 26 – 56).

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Colvin, Jr. et al. discloses a transmitter. However, Colvin, Jr. et al. fails to disclose the interaction chamber being a capillary. Lemelson discloses an autonomous device (Figure 10) configured for being capable of passing through a body lumen having a capillary for receiving and analyzing an endo-luminal sample (Col. 22, lines 37 – 52). Furthermore, Lemelson discloses the capillary as being equivalent to an interaction chamber (Col. 9, lines 25 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the interaction chamber as disclosed by Colvin, Jr. et al. with a capillary as taught by Lemelson in that Lemelson discloses capillaries and interaction chambers as being functionally equivalent and therefore the same.

3. Claims 1 - 2, 7 – 18, 21 – 38 and 40 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/53792 A2 to Given Imaging Ltd. in view of U.S. Patent No. 6,330,464 to Colvin, Jr. et al., and further in view of U.S. Patent No. 5,993,378 to Lemelson.

In regards to claims 1 – 2, 7 – 18, 21 – 38 and 40 – 46, Given Imaging Ltd. Discloses an autonomous device capable of passing through a body lumen and determining in vivo conditions, the device having at least one interaction surface (54) for receiving a sample while in vivo, the surface having at least one indicator immobilized thereon for reacting with the sample for generating optical changes (Page 6, lines 14 – 19); at least one illumination source (51) for illuminating the surface; and at least one optical detector (55) for detecting optical changes occurring on the surface. The surface is transparent in the wavelength of illumination (Page 11, line 30). Given Imaging Ltd. discloses the optical detector being an imager for obtaining images of the interaction surface and of the body lumen in which the device is disposed and producing video signals thereof (Page 11, line 29 – Page 12, line 3) . The device includes a transmitter for transmitting the video signals and a receiving system for receiving the video signals (Page 11, line 26). Given Imaging Ltd. discloses the device being suitable for passing through a GI tract and receiving a sample from the GI

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environment (Page 11, line 32 – Page 12, line 2). Given Imaging Ltd. discloses the device being a swallowable capsule. However, Given Imaging Ltd fails to disclose the interaction surface being an interaction chamber. Colvin, Jr. et al. discloses an autonomous device for determining in vivo condition. Colvin, Jr. et al. teaches the device having an indicator located within an interaction chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interaction surface as disclosed by Given Imaging Ltd. to include an interaction chamber containing the indicator as taught by Colvin, Jr. et al. in order to help protect the indicator while in use (Col. 25, lines 50 – 61). Lemelson discloses an autonomous device (Figure 10) configured for being capable of passing through a body lumen having a capillary for receiving and analyzing an endo-luminal sample (Col. 22, lines 37 – 52). Lemelson discloses the capillary as being equivalent to an interaction chamber (Col. 9, lines 25 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the interaction chamber as disclosed by Given Imaging Ltd. in view of Colvin, Jr. et al. with a capillary as taught by Lemelson in that Lemelson discloses capillaries and interaction chambers as being functionally equivalent and therefore the same.

4. Claims 19, 20, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,330,464 to Colvin, Jr. et al. in view of WO 01/53792 A2 to Given Imaging Ltd., and further in view of U.S. Patent No. 5,993,378 to Lemelson.

In regards to claims 19, 20, 38 and 39, Colvin, Jr. et al. discloses a system for determining in vivo conditions, the system having two opposing ends; two interaction chambers (14', 14'') for containing a sample while in vivo, the chambers each having at least one indicator therein for reacting with the sample for generating optical changes in the two chambers (Col. 12, line 65 – Col. 13, line 2); at least one illumination source (18) for illuminating the two chambers; two sensors (20-1,

20-2) for detecting optical changes occurring in the interaction chambers and producing signals thereof, a transmitter for transmitting the signals to a receiving system, wherein the two chambers and sensors are positioned at an opposing end of the system. Colvin, Jr. et al. discloses a battery (40) for providing power to the system. However, Colvin, Jr. et al. fails to disclose the sensors being image sensors for obtaining in vivo images of the interaction chambers and the surrounding environment. Given Imaging Ltd. discloses a system for determining in vivo conditions where the sensor can be an optical detector or an image sensor for detecting optical changes and for obtaining in vivo images of the interaction surfaces and the surrounding environment (Page 6, line 30 – Page 7, line 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the optical sensors as disclosed by Colvin, Jr. et al. to be an image sensor as taught by Given Imaging Ltd. in that Given Imaging Ltd. teaches the optical sensor and the image sensor as functionally equivalent and therefore interchangeable. Furthermore, Lemelson discloses an autonomous device (Figure 10) configured for being capable of passing through a body lumen having a capillary for receiving and analyzing an endo-luminal sample (Col. 22, lines 37 – 52). Lemelson discloses the capillary as being equivalent to an interaction chamber (Col. 9, lines 25 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the interaction chamber as disclosed by Colvin, Jr. et al. in view of Given Imaging Ltd with a capillary as taught by Lemelson in that Lemelson discloses capillaries and interaction chambers as being functionally equivalent and therefore the same.

5. Claims 48 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,993,378 to Lemelson in view of WO 01/53792 A2 to Given Imaging Ltd.

In regards to claims 48 – 52, Lemelson discloses an autonomous device in the form of a capsule (Figure 10) capable of passing through a body lumen (Col. 9, lines 30 – 31) including at least

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one interaction chamber containing a sample while in vivo including two openings (Col. 22, lines 42 – 46); an illumination source (Col. 22, lines 53 – 54); an optical detector in the form of an imager (Col. 22, lines 54 – 55); a transmitter (Col. 22, lines 63 – 67) and a micro-pump (Col. 22, lines 49 – 52). Lemelson discloses optically analyzing the interaction chamber (Col. 9, lines 27 – 28).

However, Lemelson fails to disclose an indicator being located in the interaction chamber for reacting with the sample for generating optical changes. Given Imaging Ltd. an autonomous device in the form of a capsule utilizing an indicator for reacting with a sample for generating optical changes (Page 6, lines 7 – 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interaction chamber as disclosed by Lemelson to include an indicator as taught by Given Imaging Ltd. so that qualitative and quantitative results of a desired substance can be obtained (Page 6, lines 23 – 29).

### *Response to Arguments*

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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